

Message Text

UNCLASSIFIED

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53

ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 EB-07 COME-00 /032 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:PFF

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

EUR/EE:KBROWN (INFO)

EUR/CE:RCASSAGRANDE (INFO)

EUR/NE:JSHUMATE (INFO)

EUR/NE:CSCHALLER (INFO)

----- 008819

R 152121Z SSP 76

FM SECSTATE WASHDC

TO AMEMBASSY PRAGUE

AMEMBASSY BONN

AMEMBASSY LONDON

AMEMBASSY DUBLIN

UNCLAS STATE 228610

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, CZ, GW, UK, EI

SUBJECT: FDA REPRESENTATIVE PROVIDING TECHNICAL AND
CONSULTATIVE ASSISTANCE TO FOREIGN DRUG MANUFACTURERS

1. FDA ADVISES THAT JAMES BUMILLER, OFFICE OF THE
EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS, WILL BE IN
EUROPE OCTOBER 30-NOVEMBER 29, 1976.
2. MR. BUMILLER WILL VISIT SIX PHARMACEUTICAL FIRMS TO
DETERMINE IF THEIR FACILITIES AND OPERATIONS ARE IN
ACCORDANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGU-
LATIONS AND WILL REPORT ANY SIGNIFICANT DEVIATIONS WHICH
WOULD HAVE ADVERSE EFFECT UPON THE SAFETY AND/OR EFFICACY
OF PHARMACEUTICALS BEING EXPORTED TO THE UNITED STATES.
3. ITINERARY IS AS FOLLOWS:
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OCTOBER 29, 1976 - DEPART WASHINGTON, D.C. TO PRAGUE,
CZECHOSLOVAKIA.

NOVEMBER 1, 1976 - VISIT WITH CHEMAPOL AND SPOFA OFFICIALS.

NOVEMBER 2, 1976 - TRAVEL PRAGUE TO OPAVA.

NOVEMBER 3-5, 1976 - VISIT GALEANA.
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NOVEMBER 6, 1976 - TRAVEL OPAVA TO PRAGUE.

NOVEMBER 8, 1976 - TRAVEL PRAGUE, CZECHOSLOVAKIA, TO
FRANKFURT, WEST GERMANY.

NOVEMBER 9-11, 1976 - VISIT CHEMIEWERK, HOMBURG.

NOVEMBER 12 - TRAVEL FRANKFURT, WEST GERMANY TO LIVER-
POOL, ENGLAND.

NOVEMBER 15-17, 1976 - VISIT DISTA.

NOVEMBER 18, 1976 - TRAVEL LIVERPOOL, ENGLAND TO DUBLIN,
IRELAND.

NOVEMBER 19, 20, 1976 - VISIT LINSON.

NOVEMBER 22-23, 1976 - VISIT LAWRENCE.

NOVEMBER 14, 1976 - TRAVEL DUBLIN TO CORK.

NOVEMBER 25-27, 1976 - VISIT CHEMIEBIOTIC (A AND P).

NOVEMBER 29, 1976 - DEPART CORK, IRELAND TO WASHINGTON, D.C.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED. ROBINSON

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NNN

*** Current Handling Restrictions *** n/a

*** Current Classification *** UNCLASSIFIED

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TAGS: EIND, ETRD, TBIO, CZ, EI, GE, UK, US, FDA, OGEN, (BUMILLER, JAMES)
To: BONN
LONDON
MULTIPLE
PRAGUE
Type: TE

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